STATE OF ILLINOIS
DEPARTMENT OF PUBLIC AID

MEDICAID 1115 RESEARCH AND DEMONSTRATION WAIVER APPLICATION:

A PHARMACEUTICAL BENEFIT
FOR ILLINOIS' LOW-INCOME SENIORS -
PROVIDING ENHANCED ACCESS TO PRIMARY CARE

JULY 31, 2001

ILLINOIS DEPARTMENT OF PUBLIC AID
1115 DEMONSTRATION WAIVER APPLICATION

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I. Executive Summary

The State of Illinois Department of Public Aid (the Department) proposes to provide comprehensive pharmacy benefits to low-income seniors. Under this program, seniors at or below 250 percent of the Federal Poverty Level will receive a pharmacy benefit under the State's Medicaid program through a Section 1115 Research and Demonstration waiver. Individuals eligible for this waiver program are not eligible for benefits under the current Medicaid rules.

Illinois has made a significant effort to date to provide a pharmacy benefit to low-income seniors. However, the current benefit through the State-only program is a restricted benefit providing for a limited number of chronic and catastrophic drugs. Providing an enhanced comprehensive pharmacy benefit under the proposed waiver will make the benefit available to a greater portion of the elderly population. Currently, many seniors have only limited primary care benefits because Medicare does not cover prescription drugs. For the first time, this waiver will provide seniors with access to prescription drugs, thereby making their primary care benefits more comprehensive. It is anticipated that the program will serve approximately 370,000 Illinois low-income seniors.

Research has demonstrated that prescription drugs are cost-effective, as compared to hospitalization and nursing home utilization. For example, studies have estimated that every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital care expenditures. These savings relate not only to the preventive nature of some pharmaceuticals, but also to the fact that inadequate coverage of this primary care benefit causes millions of low-income seniors to reduce their use of clinically essential medications. The improper use of essential medications due to income constraints increases hospital and nursing home admissions, costing more to the health care system in the aggregate.

Undoubtedly, the lack of drug coverage for seniors under the Medicare program is one of today's most important public policy issues. While there has been much discussion regarding this most significant issue, reform on a national level has been slow. Illinois' proposed waiver, therefore, is a timely program that will fill this gap now and serve as an experiment that tests the cost-effectiveness of pharmaceutical drugs until there is a national solution.

II. Overview

Currently, many seniors' primary care benefits are limited because Medicare excludes prescription drug coverage, an integral part of comprehensive primary care. This lack of access to prescription drugs for the elderly is one of the most significant issues confronting our national health care system. A recent White House paper describing the Immediate Helping Hand initiative, which proposes giving block grants to states to provide pharmacy coverage for seniors, said:

"The most vulnerable beneficiaries have already waited too long for action. Millions of beneficiaries have modest and fixed incomes, or illnesses that make them dependent on costly medications, but they have no drug coverage that protects them against catastrophic expenses. Lack of drug coverage disproportionately affects the near poor (those not eligible for Medicaid), the oldest elderly, and beneficiaries living in rural areas. Because the incomes of these beneficiaries also tend to be lower, rising drug costs especially strain their budgets."

This situation is growing worse by the day, as the costs of prescription drugs continue to dramatically increase.

The State of Illinois is one of the many states that has taken strides to address this important issue at the state level. Illinois has been providing pharmacy benefits on a very limited scale to low-income seniors and persons with disabilities for more than 15 years. The Illinois Circuit Breaker/Pharmaceutical Assistance program began in 1985 to help seniors pay for prescription medications. This program, which is outside of the Medicaid program, has a very limited formulary and is currently available to individuals who are disabled or 65 years and older and have an income at or below 250 percent of the Federal Poverty Level Income Guideline (FPL)[i,ii] and who do not otherwise qualify for Medicaid.

The State of Illinois Department of Public Aid (the Department), the state agency that administers the Medicaid program, proposes offering an expanded, much more comprehensive pharmacy benefit to seniors 65 and older whose income is at or below 250 percent of the FPL through a Section 1115 Research and Demonstration waiver. Under this proposal, individuals will qualify for pharmacy benefits through the Medicaid program. As a result of the expanded pharmacy benefit, the number of participants in the program will significantly increase. It is anticipated that this proposal will provide increased access to a more comprehensive primary care benefit by providing pharmaceuticals to approximately 370,000 Illinois seniors.

The prescription drug benefit will be the same as that provided under the State's current Medicaid State Plan, which covers all products that are required under the Omnibus Budget Reconciliation Act of 1990. This comprehensive pharmaceutical benefit package covers all disease states.

By expanding access to prescription drugs for the elderly, Illinois intends to bridge the gap until a national reform of Medicare prescription drugs can be implemented.

The Department proposes to demonstrate that providing expanded pharmacy benefits to an expanded population will provide the following benefits:

- Help to preserve the health of the senior population by providing financial support for costly but essential drugs, thereby providing a more comprehensive primary care benefit.

- Improve the quality of life of Illinois' seniors, thereby allowing them to remain in less costly home settings and avoid expensive acute or long-term care services resulting from a lack of access to necessary drugs.

- Reduce the speed at which seniors "spend down" and become entitled to all benefits available under the Medicaid program.

- Reduce Medicaid expenditures for the dual-eligible population.

- Save the federal government money by improving the health of seniors, resulting in savings to the Medicare program.

A. History of Pharmacy Programs in Illinois

The Illinois Circuit Breaker/Pharmaceutical Assistance Program was created by the Senior Citizens and Disabled Persons Property Tax Relief and Pharmaceutical Assistance Act in 1985, as an extension to and the third benefit of, the Circuit Breaker Tax Relief Program. Initially, the purpose of the Circuit Breaker/Pharmaceutical Assistance program was to provide low-income seniors and persons with disabilities compensation for cardiovascular medications; in 1987, coverage was expanded to include medications for arthritis and diabetes. Over time, the Circuit Breaker/Pharmaceutical Assistance program has undergone numerous structural changes from expanding coverage to include medications for catastrophic illnesses, to changes in eligibility and cost-sharing requirements, to the use of additional cost-controlling techniques.[iii]

Historically, participation in the Circuit Breaker/Pharmaceutical Assistance program has been relatively small (51,823 participants in 2000[iv]) as a result of the limited formulary. With coverage, participants receive approved prescriptions for heart and blood pressure problems, diabetes, arthritis, Alzheimer's disease, Parkinson's disease, cancer, glaucoma, lung disease and smoking related illnesses only. These prescriptions are provided through pharmacies participating in the program.[v,vi]

The Illinois Department of Revenue has been responsible for the administration of the Circuit Breaker/Pharmaceutical Assistance program since its inception. To date, the funding for the Circuit Breaker/Pharmaceutical Assistance program has been provided entirely by the State in an effort to ensure that the low-income elderly receive necessary medications. The cost of the program in State Fiscal Year 2000 was approximately $50 million.

B. Aged, Blind and Disabled Eligibility Expansion

During its Spring 2000 Legislative Session, the Illinois General Assembly passed a bill that expanded Medicaid eligibility for individuals who were Aged, Blind or Disabled; the bill was subsequently signed into law by the Governor. The new law progressively raises the qualifying income threshold for the Medicaid program over a three-year period. On July 1, 2000, the threshold was increased from approximately 41 percent of the FPL to 70 percent; on July 1, 2001, the law raised the threshold to 85 percent of the FPL; on July 1, 2002, the law increases the qualifying income threshold to 100 percent of the FPL. When fully implemented, this eligibility expansion will make over 100,000 individuals eligible for full Medicaid benefits, including all primary care services.

C. Prescription Drugs and the Elderly

The lack of drug coverage for seniors under the Medicare program is one of today's most important public policy issues. Although seniors represent approximately 9 percent of the United States population, they account for one-third of the drug expenditures.[vii] As people in the United States live longer, the proportion of senior citizens in this country will continue to grow. Drug costs are also on the rise. At the same time, benefits from Social Security and Supplemental Security Income have increased at a much slower pace (only 1.3 percent in 1999).[viii] The combination of a larger elderly population and more expensive drugs could be very costly to both seniors and the government if state and federal payers of health care, particularly Medicare, do not develop a reasonable way to provide seniors with comprehensive primary care benefits by providing drug coverage soon.

Drug coverage has been repeatedly linked to health status. Sixty-four percent of Medicare beneficiaries have no supplemental insurance coverage for outpatient drugs. These individuals tend to be sicker than those with some type of supplemental insurance. Of those without supplemental drug coverage, 40 percent report that their health is only fair or poor; only 23 percent of those with supplemental drug coverage report a fair or poor health status.[ix] Until a national solution to the lack of Medicare coverage can be implemented, Illinois proposes to partner with the Centers for Medicare and Medicaid Services (CMS) to address this problem in Illinois.

As health care costs continue to rise for all Americans, access to drugs for this population, a basic primary care benefit, will become increasingly relevant. The lack of access to essential medications for the chronically ill and those with acute diseases is likely to increase hospital and nursing home costs, which eventually affects every tax-paying member of society.

Use of prescription drugs not only improves the quality of primary care services, but is cost-effective as compared to hospitalization or long-term care. For example, studies have estimated that every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital care expenditures. These savings relate not only to the preventive nature of some pharmaceuticals, but also to the fact that inadequate coverage of this primary care benefit causes

millions of low-income elderly to reduce their use of clinically essential medications. The improper use of essential medications due to income constraints increases hospital and nursing home admissions, increasing health care costs in the aggregate.

III. Proposed Pharmacy Waiver Program Design

A. Eligibility Requirements

State Medicaid programs may have two types of eligibility categories: categorically needy and medically needy. Both categories are established under the Social Security Act. Certain groups, such as pregnant women or the elderly, are considered categorically eligible if they also meet income criteria based on the FPL. "Medically needy" eligibles are those that would be categorically needy except for their slightly higher income and resources, but who cannot afford to pay their medical bills.

For the purposes of this waiver program, all individuals will be considered categorically needy and eligible for prescription drug services.

To be eligible for prescription drug services under this 1115 Research and Demonstration waiver program, individuals must:

- Meet existing Medicaid residency requirements;
- Meet existing Medicaid rules on citizenship and immigration status;
- Meet existing Medicaid rules regarding inmates and residents of public institutions;
- Be age 65 or older;
- Have a household income at or below 250 percent of the FPL, using existing Medicaid rules for counting income; and
- Pay the applicable annual enrollment fee (with the exception of individuals with private insurance).

There will be no asset test related to eligibility for the waiver program and there will be no estate claims for services provided under this waiver.

B. Application Process for Pharmacy Waiver Benefits

The application process for eligibles in this 1115 Research and Demonstration waiver program will be comprised of the following components:

- A separate application will be developed for the waiver program; this application will be for the waiver program only.

- Illinois Medicaid will not review waiver program applications for eligibility for any other Medicaid programs. The application will contain a statement advising applicants that individuals should complete a full Medicaid application if they are interested in any other benefits.

- Applications will be processed by a central unit. Illinois may use an outside contractor to process applications to determine eligibility.

- Applications will be accepted by mail and, in the future, the Department may accept applications by telephone, electronically, over the Internet or by other means as appropriate.

- Near the end of an individual's year of eligibility, the Department will send a renewal application. To continue coverage, the renewal application must be filed in a timely manner and receive approval. The individual must also pay the annual enrollment fee.

- Upon enrollment, waiver program recipients will receive an identification card distinct from a normal Medicaid card. This card will be replaced annually when the individual renews enrollment in the program. Recipients must present the identification card at the pharmacy when purchasing prescription drugs.

Because the eligibility requirements for the proposed 1115 Research and Demonstration waiver program are essentially the same as those for the current state-only Pharmaceutical Assistance Program (except that there are disabled individuals under age 65 in the state-only program), the Department plans to automatically enroll all individuals in the Pharmaceutical Assistance Program who are 65 and older in the waiver program. These individuals will not be required to submit a new application until their existing yearly enrollment period expires.

C. Enrollment Periods

Enrollment periods for eligibles will be as follows:

- Once determined eligible for the waiver program, an individual will remain eligible for 12 months from the date of initial eligibility, regardless of changes in income.

- Eligibility for benefits will be prospective only; there will be no retroactive eligibility.

- For eligibility determinations made prior to the fifteenth day of a month, eligibility will begin on the first day of the following month. For eligibility determinations made after the fifteenth day of a month, eligibility will begin on the first day of the second month following the month in which the determination was made. (For example, for an eligibility determination made January 10, program eligibility will begin February 1; for an eligibility determination made January 20, program eligibility will begin March 1.)

D. Enrollment Caps

The Department anticipates that the waiver program, when fully implemented, will serve approximately 370,000 individuals. Cost neutrality for the waiver program is predicated on this number of participants. Should the program prove to be such a success that this enrollment number is greatly exceeded, or if the average cost per individual is significantly greater than originally anticipated, the program will be underfunded at the state level and the Department will be unable to demonstrate cost neutrality. Therefore, to protect the Department from an unforeseen spiraling of program costs, we request that program participation be capped at 370,000. Should waiver program costs prove to be lower than originally estimated, the Department may choose not to implement this cap.

E. Benefits

The waiver program pharmacy benefit will be as comprehensive as that provided in the current Illinois Medicaid State Plan, which covers all products that are required under the Omnibus Budget Reconciliation Act of 1990 and all disease states, including over-the-counter drugs with a doctor's order. This pharmacy benefit will inherently enhance primary care benefits for this waiver population.

As an alternative benefit, eligible individuals with private insurance coverage for pharmaceuticals may choose to receive a monthly rebate check rather than a direct pharmaceutical benefit. This will reimburse seniors for out-of-pocket expenses, including premiums, deductibles and co-payments.

F. Cost Sharing

Participants in this program will share the costs of waiver program benefits. Cost sharing will include annual enrollment fees and copayments. Copayment amounts will increase for an individual after their annual expenditures exceed a specified amount. The following describes the initial cost sharing features in more detail:

i. *Annual Enrollment Fees*

Participants will pay an annual enrollment fee that is based on income.

- Participants with a household income (based on household size) below the FPL will be required to pay an annual enrollment fee of $5.

- Participants with a household income equal to or greater than the FPL will be required to pay an annual enrollment fee of $25.

ii. *Copayments*

The following copayments will apply:

- Participants with a household income below the FPL will not be required to pay a copayment for prescriptions until the benefit threshold explained below is reached.

- Participants with a household income equal to or greater than the FPL will be required to pay a $3 copayment per prescription for legend drugs.

- Participants will not be required to pay a copayment for over-the-counter drugs.

- The program will pay for each participant's prescriptions, net of the $3 copayment amount if applicable, until the accumulated total paid by the program reaches a pre-specified threshold for the 12 month eligibility period. Once total annual expenditures reach the threshold amount, a participant will be required to pay 20 percent of the cost of each prescription. This 20 percent amount will be in addition to the $3 copayment amount required for those at or above the FPL.

- If a generic drug is available and the participant wants a brand name drug, the program will pay the generic price, less the applicable copayment. The participant will pay, in addition to the copayment applicable to the generic drug, the difference between the generic price and the brand name price, unless the drug is a federally defined narrow therapeutic index drug and substitution is not permitted because the physician has indicated "brand medically necessary".

iii. *Future Adjustments to Cost Sharing*

The Department proposes that it be granted flexibility under the waiver to modify, within specified limits, cost sharing requirements during the term of the 1115 Research and Demonstration waiver program to control program costs. If modifications were warranted, the upper limit for the initial per prescription copayment would be $10.00. If modified, the lower limit for the threshold at which the percentage copayment becomes applicable would be $1,000.00. Within the per prescription copayment limit specified above, the Department may

institute a copayment structure to create an incentive for providers to prescribe drugs that are medically and economically appropriate. Also, copayments may be waived or reduced for individuals who purchase their pharmaceuticals through one of the various mail order options.

G. Coordination with Other Medicaid Programs

The following are stipulations regarding coordination between the Medicaid program and the 1115 Research and Demonstration waiver program:

- As discussed previously, the Department will not review waiver program applications for eligibility for other Medicaid programs. The application will contain a statement advising applicants that they should complete a full Medicaid application if they are interested in any other benefits.

- Should an individual's income decrease so that they would be fully Medicaid eligible, that individual would have to submit a complete Medicaid application and be determined eligible through existing procedures if they wanted full Medicaid benefits.

- The enrollment fee is not refundable to individuals who become fully Medicaid eligible while enrolled in the waiver program.

- Individuals cannot spend down to become eligible for the waiver program.

- Individuals who are terminated from the waiver program or who fail to re-enroll will not be reviewed for eligibility for other Medicaid programs prior to termination.

H. Benefit Management Strategies

To further enhance the primary care benefits that this waiver will provide to Illinois seniors, the Department plans to implement a number of benefit management strategies to enhance quality of care and cost-effectiveness within the waiver program. The Department is considering the following benefit management strategies.

i. *Concurrent Drug Utilization Review (DUR)*

Concurrent Drug Utilization Review (DUR) can be used to improve the quality of care provided to recipients. At the point of sale, as the pharmacist prepares to fill the prescription, an automated real-time concurrent DUR screening is performed. The screen provides the pharmacist with information regarding potential inappropriate drug utilization, for example:

- Therapeutic duplication

- Drug-disease contraindications

- Drug-drug interactions
- Incorrect drug dosage or duration of drug treatment
- Drug-allergy interaction
- Clinical abuse/misuse

Because seniors often see multiple providers for a variety of conditions, the concurrent DUR element of this waiver is crucial to improving the quality of primary care and keeping seniors out of a hospital or other institutional setting. Currently, if a senior fills his or her prescriptions at multiple pharmacies, for example, one near the cardiologist's office and one near the Primary Care Physician's office, these pharmacies may not be electronically linked to determine whether there is the potential for a drug interaction between a new prescription and an existing medication. Under the waiver, one system will be used for concurrent DUR across all participating pharmacies, thereby improving the quality of care for seniors.

ii. *Drug Protocol Management*

Illinois is also considering integrating a drug protocol management system at the point-of-sale. The goal of drug protocol management is to limit inappropriate utilization of drugs, thereby improving quality of care. This is mainly performed through a step-therapy approach for selected interventions. For example, Gastroesophageal Reflux Disease (GERD) is a common diagnosis which can be treated by a variety of pharmaceuticals. Over-the-counter antacids are considered a first-line therapy, followed by H-2 blockers such as Tagamet if antacids do not sufficiently control symptoms. For patients not responding to these first or second line therapies, a proton pump inhibitor medication, such as Prilosec, may be appropriate. Through the drug protocol management system, for select interventions, the system screens the claim history and if a patient has not yet tried a first line therapy, the physician or pharmacist must first obtain prior authorization in order to obtain a second-line drug.

The prior authorization system can also be used for a number of other selected interventions. For example, it can require a participant to obtain prior authorization for a brand medication prescription when a generic is available, or it can be used as a formulary management tool, by requiring prior authorization for a non-preferred medication.

iii. *Retrospective DUR*

Illinois is considering the implementation of a senior-focused retrospective DUR program with the goal of improving quality of care. Such a program would encourage the review and simplification of complex drug therapy in patients receiving multiple maintenance medications. The goal of such a program is to help seniors manage complex medication regimens by encouraging physicians to coordinate care and simplify drug therapy regiments, if appropriate.

iv. *Disease Management and Drug Choice Education*

The waiver program may include both a client education and a three-tiered physician education component. The Department plans to implement the physician and client information programs throughout the Illinois Medicaid program, not just for the waiver program population. Therefore, these programs are not considered an exclusive part of this waiver application, but the waiver program population will be incorporated into these programs.

IV. Waiver Program Implementation and Administration

A. Administering Agency

The Department may administer the waiver program through an interagency agreement with the Illinois Department of Revenue. Portions of the program may be administered by private entities under contract with the State.

B. Financing

Prescription drug services under the 1115 Research and Demonstration waiver program will be funded jointly through State funds and matching federal monies.

Additional program revenue for the 1115 Research and Demonstration waiver program will come from the annual enrollment fees mentioned previously and monies from the drug rebate program. Illinois currently has drug rebate agreements with all pharmaceutical companies participating in the Medicaid rebate program pursuant to Section 1927 of the Social Security Act. This program will continue to rely on these agreements in future periods.

C. Provider Network

The 2,821 Pharmacies currently enrolled in the Illinois Medicaid program (98 percent of licensed pharmacies) will fill prescriptions for waiver program recipients as well. Access to pharmacies for the waiver program will be readily available as most pharmacies in Illinois participate in the Illinois Medicaid program.

D. Implementation Schedule

The Department expects the waiver program to last for five years and is aggressively pursing an implementation date of January 1, 2002. Since many of the program design features are already in place, the Department is confident that the waiver program will be operational by the target date.

E. Early Termination of the Waiver Program

Illinois reserves the right to end this 1115 Demonstration Waiver should actual experience show that it is not cost effective or cost neutral. Further, Illinois may amend or terminate this program should a federal program provide access to prescription drugs for all or part of the waiver population. Illinois residents will not be disadvantaged with regard to their participation in any such federal program as a result of the state's decision to terminate this waiver program. Illinois may also choose to seek a Medicare waiver for the State in order to coordinate the programs.

V. Waivers Requested

This demonstration program requires waivers from Title XIX of the Social Security Act. Section 1115(a)(1) of the Social Security Act permits the Secretary of the Department of Health and Human Services (the Secretary) to waive compliance with any of the requirements of Section 1902 of the Social Security Act, which specify State Medicaid Plan requirements, to the extent and for the period necessary to carry out the demonstration project. Section 1115(a)(2) permits Illinois to regard as expenditures under the State plan costs of the demonstration project which would not otherwise receive a federal match under section 1903 of the Social Security Act. These provisions allow the Secretary to waive existing program restrictions and provide expanded eligibility and/or services to individuals not otherwise covered by Medicaid. Illinois requests that the Secretary waive the following Title IX provisions:

- **Eligibility.** Illinois requests the Secretary to waive Sections 1902(1), 1903(f) of the Social Security Act and Sections 435.100 *et seq.* of Title 42 of the Code of Federal Regulations (CFR). These sections prohibit Federal Financial Participation to states that implement eligibility standards in excess of the stated maximums. Illinois seeks a waiver to expand eligibility for pharmaceuticals to non-categorical individuals with incomes at or below 250 percent of the FPL.

- **Comparability.** Illinois requests the Secretary to waive Section 1902(a)(10)(B) of the Social Security Act and 42 CFR Sections 440.230 through 440.250. These sections require the amount, duration, and scope of services be equally available to all recipients within an eligibility category and be equally available to categorically eligible and medically needy recipients. Illinois seeks a waiver of these provisions to offer a comprehensive drug benefit to the expanded population. Illinois also seeks to eliminate enrollment fees and copayments for those waiver eligibles with private insurance to encourage them to maintain private coverage.

- **Copayments.** Illinois requests the Secretary to waive Section 1916(b)(2)(i) that requires copayments to be identical among all Medicaid recipients. Illinois seeks a waiver to establish copayment amounts higher than those used for the general Medicaid population and to waive copayments for individuals that maintain private health insurance.

- **Retrospective benefits.** Illinois requests the Secretary to waive Section 1902(a)(34) of the Social Security Act and 42 CFR 435.914 that require a state to retrospectively provide medical assistance for three months prior to the date of application in certain circumstances. Illinois requests a waiver to establish the effective date for demonstration participants as the date of enrollment as determined in accordance with Section III(C), above.

- **Eligibility.** Illinois requests the Secretary to waive Sections 1902(a)(17), 1902(a)(10)(A)(ii)(I) and (II) of the Social Security Act and 42 CFR Part 435, Subparts G, H and I. These sections establish standards for taking into account income or resources of individuals who are not receiving assistance under Temporary Assistance to Needy Families (TANF) or Supplemental Security Income (SSI). All TANF and SSI recipients are entitled to Illinois Medicaid benefits. People who are ineligible for TANF or SSI benefits will be eligible for the demonstration pharmacy program if they meet age and income requirements, however, there will not be an asset test applied to the demonstration population. Illinois, therefore, requests to waive the standards for taking into account resources in determining eligibility for this demonstration project.

- **Administration.** Illinois requests the Secretary to waive Section 1902(a)(5) of the Social Security Act and 42 CFR 431.10. These sections prohibit the State from contracting with a private contractor to make eligibility determinations for Medicaid.

In addition, Illinois requests that, under the authority of Section 1115(a)(2), expenditures for the items identified below (which are not otherwise included as expenditures under Section 1903) be regarded as expenditures under Illinois' Medicaid State Plan:

- Expenditures to provide and receive comprehensive pharmacy benefits to seniors age 65 and older whose income is at or below 250 percent of the FPL.

- Administrative expenditures for demonstration participants including but not limited to collecting program participants' fees, enrolling pharmacies, producing and distributing enrollment cards to program participants, responding to client inquires, collecting third-party insurance information and evaluation and monitoring of this demonstration waiver.

Illinois requests the right to consider other waivers to implement the proposed pharmacy program, if necessary.

VI. Program Implications for the Private Health Insurance Industry

A. Crowd-Out from Expanded Pharmacy Services

Supplemental private insurance, whether former employer-based or individually purchased, is becoming more expensive each year. As a result, the number of seniors with supplemental drug coverage is on the decline. According to a recent *New York Times* article:

"*Fewer employers are offering retiree health coverage, and Medigap is increasingly scarce and expensive.*"[x]

The Current Population Survey indicates that approximately 20 percent of the eligible population for this program may have benefits available to them from employer-sponsored private insurance. Illinois does not believe that implementation of this program will have a significant impact (crowd-out) on the number of individuals that maintain such insurance.

B. Experiences from the State Children's Health Insurance Program Expansions

Crowd-out concerns surfaced in the past as a result of various Medicaid expansions and the implementation of the State Children's Health Insurance Program (SCHIP). However, crowd-out with SCHIP appears to have been minimal. For example, when implementing MinnesotaCare, a program similar to SCHIP,[xi] the state implemented various strategies including a waiting period for enrollment and premiums more expensive than private insurance for the higher income population.[xii] A 1998 survey of the program found that just 7 percent of the respondents gave up their private insurance to enroll in the publicly subsidized program;[xiii] the private insurance market was not significantly affected. Other states such as Rhode Island and Tennessee have experienced similar outcomes in their publicly subsidized programs with fewer crowd-out strategies in place. The lack of crowd-out has been so minimal that CMS substantially eased requirements for certain anti-crowd-out strategies in its final SCHIP regulations over what had been required by the proposed regulations.

Illinois' approach to crowd-out in SCHIP has been to provide an incentive for families to maintain their children's health insurance through a rebate program as an alternative to direct benefits. Eligibility for the direct benefits in SCHIP included a three-month waiting period for families that voluntarily dropped private insurance. Evidence suggests that the rebate program was a successful strategy. Of applications processed, only 0.04 percent were denied for voluntarily dropping private insurance. These denials represented only 0.24 percent of all denials.

The pharmacy waiver program has been designed to provide similar financial incentives for seniors to maintain pharmacy benefits they already have. The successful Illinois SCHIP strategy is expected to be equally successful in the pharmacy waiver program.

With respect to the proposed waiver, crowd-out is less of a potential problem simply because there is less to crowd-out. Prescription drug coverage is by far the single most significant gap in coverage for seniors.

Nevertheless, Illinois is designing its program to minimize crowd-out. Crowd-out can occur if:

- An individual decides to drop private coverage for a public option.
- A pension plan or other private insurer decides to drop or alter coverage for enrollees.

Features of the proposal that will prevent crowd-out are:

- Individuals with pension-based coverage of pharmaceuticals will have that benefit as part of a comprehensive insurance benefit. Because the proposed waiver provides only a pharmacy benefit, there is limited inducement to drop comprehensive insurance.
- To create a further incentive for individuals to maintain private insurance, Illinois will offer an alternative rebate benefit.
- Illinois plans to have cost sharing provisions that are higher than normally found in Medicaid programs to make the benefit more comparable to private insurance.

Because of the income limitation on eligibility for the waiver, it is not expected that many pension plans will be induced to drop pharmaceutical coverage since it would leave all enrollees over 250 percent of the FPL without a viable option for coverage.

It is important to consider that crowd-out strategies could be difficult to administer or difficult to implement given the financial constraints on the program.[xiv] It should be emphasized again, however, that Illinois does not expect the crowd-out phenomenon to occur with the implementation of this proposed waiver program.

VII. Budget and Cost-Effectiveness Analysis

Research shows that appropriate and necessary use of pharmaceuticals improves the health of seniors. Studies have estimated that every dollar spent on pharmaceutical coverage is associated with a $2.10 to $4.00 reduction in hospital care expenditures.[xv,xvi,xvii] For the Medicare program, spending more on prescription drug coverage could save the Medicare trust funds a great deal more in other coverage areas; for the Medicaid program, savings could be realized as a result of a decrease in the need for hospital, long-term care and other related medical services.

Findings released in 1991 show that a New Hampshire policy limiting the number of prescription drugs to seniors resulted in significant cost increases to its Medicaid program.[xviii] Although the cost the state paid for pharmaceuticals dropped 35 percent almost one year after the

implementation of the limitation, admissions to nursing homes increased 60 percent. The state also saw increases in hospital stays, visits to community mental health centers and emergency mental health services.[xix, xx] When the limitation was removed, total health care costs dropped and admissions to nursing homes returned to their original level.[xxi]

The absence of pharmaceutical insurance coverage, a basic primary care benefit, causes millions of low-income elderly to reduce their use of clinically essential medications. This improper use of essential medications increases hospital and nursing home admissions, decreases the quality of primary care and results in increased health care system costs in the aggregate.[xxii] Additionally, pharmaceutical drugs may be the only treatment for an illness where no other treatment exists.

For most people, having to make a decision to purchase food or essential medication is not a common occurrence. But for those elderly who do not qualify for state Medicaid programs and who cannot afford to purchase private insurance for prescription drugs, choosing between food and prescription drugs may not be unusual. Data released in 1999 in the *New England Journal of Medicine* showed that:

"*…among Medicare beneficiaries with incomes less than $10,000 [excluding Medicaid eligibles], almost two-thirds have no drug coverage and purchase only half as much medications as those with employer coverage despite being sicker."* [xxiii]

It is hard to quantify how elastic low-income seniors' demand is for prescription drugs, but certainly this research implies that as money becomes tighter, people must choose between the immediate needs of food and housing and the more long-term necessity of medicating a chronic illness; for example, taking a blood pressure medication to prevent the future onset of heart disease.

Improved access to a more comprehensive primary care benefit for low-income seniors, through prescription drugs, will benefit both state and federal health programs – Medicare will save from reduced hospitalization rates and Medicaid will realize savings from reduced rates of increases in hospital, nursing home and other medical services utilization.[xxiv] Consequently, a national program that divides the costs of coverage between state and federal governments, like Medicaid, could be a rational solution to providing access to prescription drugs for low-income seniors.

The Department has estimated the potential cost savings under this proposed waiver program. Based on preliminary estimates, the Department projects that it will not increase its overall Medicaid expenditures for the Aged population, 65 and older, when increasing primary care benefits by expanding the pharmacy program under this proposal. Budget neutrality will be achieved by reducing the rate of increase in the utilization of non-pharmacy related services provided to this population (hospital, nursing facility and other non-pharmacy medical services). The savings realized by reducing the rate of increase in non-pharmacy Medicaid services for this population will offset the costs of expanding the pharmacy benefit under this program.

This cost effectiveness analysis has been completed by projecting Medicaid expenditures for the Aged population under two separate scenarios. The first scenario, shown in Table 1, projects Medicaid Aged population expenditures, without implementation of the pharmacy waiver. The second scenario, shown in Table 2, projects Medicaid Aged population expenditures, including pharmacy expenditures assuming that the pharmacy waiver program is implemented. The assumptions under each of these scenarios are discussed separately below.

A. Without Implementation of the Pharmacy Waiver Program

Without the pharmacy waiver program, the Department estimates that its expenditures for the Aged population 65 and older during the five-year waiver period (state fiscal years 2003 through 2007) will be approximately $14.6 billion. Table 1 shows projected Medicaid Aged population expenditures, by year for the waiver period, assuming that the pharmacy waiver is not implemented.

Amounts shown in Table 1 for Aged population expenditures are based on actual state fiscal year (SFY) 2000 average expenditure data for all services provided to the Aged population. Average numbers of individuals served were increased from SFY 2000 at a rate of 5 percent per year, which reflects historical average annual increases, along with projected population increases resulting from previously enacted legislation raising the income standard for the Aged population. Annual expenditures were increased from SFY 2000 at a rate of 5.5 percent per year, also based on historical increases.

B. With Implementation of the Pharmacy Waiver Program

The analysis of expenditures with the waiver program includes two components. First, Aged population expenditures were projected taking into consideration reduced Medicaid utilization resulting from anticipated diverted eligibles. Second, expenditures under the pharmacy program were estimated. Both of these components are discussed separately.

i. *Projected Aged Population Expenditures with Implementation of the Waiver Program*

With implementation of the pharmacy waiver, the Department estimates that it will be able to divert approximately 7,500 Aged eligibles each year from the Medicaid program. This estimate is based on the assumption that providing pharmacy benefits will improve the quality of primary care by preventing catastrophic illnesses requiring institutionalization of persons aged 65 and older, and that those individuals will become Medicaid eligible less quickly. It also assumes that those individuals not necessarily at risk of institutionalization will also maintain their own financial resources for a longer period of time, making them eligible for Medicaid benefits less quickly. With this reduction in Medicaid utilization for the Aged population, the Department projects total Medicaid expenditures for the Aged population will be approximately $12.6 billion over the waiver period. This is a cumulative reduction of more than $2 billion over the waiver period.

Table 2 shows the calculation of Medicaid expenditures for the Aged population taking into consideration the diversion of individuals, but using the same rate of increase assumptions used in Table 1.

ii. *Projected Pharmacy Expenditures Under the Pharmacy Waiver Program*

The Department has projected that, when fully implemented under this proposed waiver, these pharmacy benefits will be provided to approximately 370,000 seniors.

The Department estimates that net pharmacy expenditures will be approximately $996 per year for these individuals in the first year of the waiver period, increasing to $1,635 per individual per year by the fifth year of the waiver period. These amounts are based on actual gross pharmacy expenditures of $1,291 for SFY 2000, inflated at a rate of eight percent for SFY 2001, and at a rate of 15 percent per year for SFY 2002, and through the end of the waiver period. Gross expenditure amounts are adjusted to take into consideration the following projected cost sharing amounts and other reductions:

- Reduced costs for those individuals who already receive pharmacy benefits through private insurance.
- Enrollment fees of $25 per year.
- Copayments of $3 per prescription.
- Reduction in the over-utilization of drugs and choice of less costly drugs because of cost sharing requirements.
- Adjustment to the costs paid by the Department resulting from cost sharing.

It is assumed that enrollment in the pharmacy program will occur over a four year period, with approximately 194,000 enrollees in the first year, increasing ratably to approximately 370,000 by the fourth year.

C. Summary of Cost-Effectiveness

With the pharmacy waiver, total combined expenditures for the Aged population and the expanded pharmacy population will not exceed what expenditures would be for the Aged population without the expanded pharmacy benefit. This expenditure offset will be accomplished by reducing the rate of growth in the Aged population for the waiver period, as a result of improved health of this population, and by a reduction in the number of individuals in this population that spend down to Medicaid eligibility.

However, an additional and significant benefit of this waiver program, not accounted for in the attached cost effectiveness analyses, is the reduction in expenditures to be realized by the Medicare Program. Similar to savings to be realized by the Medicaid program, it is anticipated that the Medicare program will achieve significant savings through reduced hospitalizations for this population group.

VIII. Program Evaluation and Monitoring

Approximately 20,000 new individuals age 65 and over enter the Illinois Medicaid program in a given year. Of these, 15,000 individuals in this demographic grouping enter a nursing facility every year. In total, individuals age 65 and over account for 318,000 general hospital inpatient days, as well as 16.3 million days in long-term care facilities.

The Department believes that by providing access to prescription drugs for this group, these individuals will acquire a basic primary care benefit, remain healthier and thus delay their eventual enrollment in Medicaid. As will be discussed in more detail below, using the current data as a baseline, the Department will partially measure the effectiveness of this waiver by the overall decrease in Medicaid hospital and long-term care stays. However, measuring the overall change in Medicaid usage will only partially demonstrate the effectiveness of this waiver as such a limited look would completely ignore resultant Medicare utilization reductions. This beneficial effect to Medicare must also be examined to completely evaluate this waiver.

Therefore, the Department further proposes to obtain Medicare current utilization data to use as a baseline, and subsequent data with which to measure cost-effectiveness. As this is data not readily available, the Department may need to partner with CMS to obtain this data on an ongoing basis. The Department believes that measuring the effect on Medicare is vital to demonstrating program effectiveness since much of this population will never become Medicaid eligible. In short, ignoring Medicare and measuring only resultant Medicaid changes will distort the evaluation process.

In sum, Illinois' proposed waiver program offers CMS the opportunity to evaluate the cost-savings for both Medicare and Medicaid, and could serve as a model for a future national drug benefit for seniors. Therefore, extensive quantitative and qualitative monitoring is warranted to identify the outcomes and implications associated with its implementation. Illinois will address the outcomes of its program by exploring three principal research questions:

1. *Health*: Does the waiver program, particularly the pharmacy benefit, improve the health of the low-income elderly population?

2. *Resources*: Is there a reduction in the utilization of non-pharmacy services for program participants as a result of the increased access to necessary medications?

3. *Health Policy*: Are the cost savings associated with this program sufficient to influence Medicare or Medicaid policy and planning?

The following sections present a framework that may be used by evaluators to analyze the outcomes of this demonstration waiver.

A. Health

Does the waiver program improve the health of the low-income elderly population covered by the waiver?

The waiver population consists of a heterogeneous group of seniors ages 65 and older. Since health is difficult to quantify and generally declines with age, accurate measurement of the health benefits associated with this demonstration project is complicated. The State, however, will use indirect indicators, such as utilization of the pharmacy benefit, and survey research methods to appraise the outcomes associated with this waiver program. The "health" principles for evaluation and their premises are:

1. Prescription drugs are an input to health that the State will be offering to its seniors ages 65 and older whose income is at or below 250 percent of the FPL. The number of seniors ages 65 and older eligible for this prescription benefit will be established. This number will serve as a baseline measure and a benchmark for evaluating the success of the program in reaching and enrolling eligible seniors.

2. Epidemiological data will be used to evaluate health outcomes for the demonstration population. Medicare data will be used to assess the age-adjusted rates of death associated with acute and chronic diseases treatable with medications. The health outcomes of Illinois residents with the pharmacy benefit will be compared to low-income seniors in other states and the nation to evaluate the program's effect.

3. Utilization rates will indirectly measure the health outcomes of the waiver participants. The basis of this measure is founded on the assumption that health is associated with reduced use of inpatient hospital services, nursing home care and other medical services provided to the Aged population. Illinois, therefore, will monitor pre- and post- demonstration inpatient hospital, nursing home utilization data and other medical services for this population. Rates will be adjusted for patient mix to more accurately assess outcomes associated with the waiver.

B. Resources

Is there a reduction in the utilization of non-pharmacy services for program participants as a result of the increased access to necessary medications?

Increasing access to prescription benefits will increase the quality of primary care and decrease adverse health outcomes associated with the lack of proper and sufficient medications for this population. Outlays incurred by providing this benefit, therefore, will be offset by the savings generated from fewer hospital and nursing home stays (and other home health/long-term care

services) and a possible decrease in emergency room services associated with improper patterns of medication usage. The "resource" principles for evaluation and their premises are:

1. Prescription drugs are a medical expense that will decrease inpatient and outpatient hospitalization rates and nursing home and other long-term care services. Prospectively, Illinois will collect and compare rates of inpatient and outpatient hospitalizations and nursing home stays between low-income seniors with and without a prescription drug benefit. Savings associated with the conservation of these healthcare resources will be calculated.

2. Proper and sufficient medication routines for some patients with chronic diseases will decrease utilization of emergency room services. Random sampling of demonstration participants' Medicare records will be used to evaluate the waiver's ability to reduce the use of emergency room services for certain disease categories. Evaluators will compare emergency room utilization rates for participants before and after their enrollment into the program.

3. Data collected throughout the demonstration will be used to compare medical service costs for people with and without a prescription drug benefit.

4. Historically, the average Aged population served by Illinois Medicaid increased at an annual rate of 5 percent. Trending will monitor the waiver program's ability to maintain or decrease the State's Aged Medicaid enrollment.

5. The demonstration program will monitor annual increases in Aged Medicaid expenditures. Historic data suggests that Illinois' Aged Medicaid expenditures increase at an annual rate of 5.5 percent. The demonstration program's ability to maintain or decrease this rate, therefore, will validate the demonstration program's success.

C. Health Policy

Are the cost savings associated with this program sufficient to influence Medicare or Medicaid policy and planning?

Many drivers, such as an aging population and research that makes more medications available to treat a broader range of morbidity, have pressured the United States health care system to realize the importance of providing a more comprehensive primary care benefit through increased access to pharmaceuticals. As can be seen from research principles and premises previously mentioned, the information gathered during the evaluation process will be useful for future health care policy and planning. Specifically, the "health policy" principles for evaluation and their premises are:

1. The waiver population consists of citizens at the Medicare qualifying age and therefore demonstration outcomes and data will be relevant to the national debate regarding the addition of a Medicare prescription benefit. Cost-effectiveness analysis will yield the value of pharmaceutical interventions for seniors.

2. The state will have improved the health of its low-income citizens and reduced costs associated with providing care to this segment of the population. This will free health care dollars that policy makers may allocate to other areas of health care.

D. Data Sources

The breadth of this Research and Demonstration project's evaluation will require data from numerous sources. The evaluation will begin at the start of the program and the evaluation process will draw on data on services used prior to and throughout the participants' enrollment in the program. Data on services used prior to enrollment in the demonstration program will allow for the formation of baseline measures and benchmarks. Data sources may include:

1. *Case Study Interviews, Focus Groups and Surveys*: Structured longitudinal interviews and/or surveys could be used to examine changes in health status and utilization of healthcare services. Surveys or interviews and focus groups could also be used to aggregate information pertaining to perceived changes in quality of life and current and historic utilization of pharmaceuticals. Survey or interview results would be used in conjunction with data obtained from other sources to evaluate the success of this Research and Demonstration project.

2. *Medicare Claims Data*: This data could be used to assist in establishing changes in utilization patterns for demonstration participants enrolled in Medicare. Medicare's comprehensive database could be used to query data for both waiver and non-waiver participants to evaluate utilization patterns and other relevant factors.

3. *Medicaid Claims Data*: Medicaid claims data for program participants will provide information regarding participant's demographics, prescriptions filled, total number of waiver participants and waiver expenditures. This data could be cross-referenced with Medicare data.

4. *Vital Statistics Reports and Census*: Data from entities such as the Illinois Department of Public Health, the Centers for Disease Control and Prevention and the Census Bureau will be used for benchmarking. These data can be used to compare outcomes of program participants, such as standardized mortality ratios, to the state as a whole and to the nation.

[i] Health and Human Services 2000 poverty guidelines are: $8,350 for an individual, $11,250 for a family of two, $14,150 for a family of three and $17,050 for a family of four.
[ii] As published annually in the Federal Register.
[iii] Ibid.
[iv] Circuit Breaker Property Tax Relief Program and Pharmaceutical Assistance Program 2000 Annual Report, Illinois Department of Revenue. Available online at: http://www.revenue.stst.il.us/circuitbreaker/pharmassist.html.
[v] Circuit Breaker - The Circuit Breaker and Pharmaceutical Assistance Programs in Perspective, available online at: http://www.revenue.state.il.us/circuitbreaker/cbpharmperspective.html
[vi] Circuit Breaker - The Pharmaceutical Assistance Program, available online at http://www.revenue.stst.il.us/circuitbreaker/pharmassist.html.
[vii] Statement by California Congressman Pete Stark, "Access to Rx Medications in Medicare Act of 1999 Fact Sheet," Available online: www.house.gov/stark/documents/106th/presciptdrugfact.html.
[viii] Soumerai, Stephen B., Ross-Degnan, Dennis, "Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action (Sounding Board.) *The New England Journal of Medicine*. 340(9): 722-728.
[ix] Ibid.
[x] Pear, Robert, "Clinton Will Seek a Medicare Change on Drug Coverage." *The New York Times*. June 8, 1999.
[xi] MinnesotaCare provides insurance to families with children up to 275 percent of the FPL and to single adults up to 135 percent.
[xii] Individuals were eligible for MinnesotaCare only if they had been uninsured for six months prior to enrolling and did not have access to a plan in the preceding 18 months. In addition, the state placed a cap on inpatient hospital services for adults, making it less enticing for individuals to give up private coverage. Finally, premiums were increased for the higher income population such that private insurance for an individual was less expensive.
[xiii] Call, Kathleen Thiede, Lurie, Nicole, Jonk, Yvonne, Feldman, Roger, and Finch, Michael D., "Who Is Still Uninsured In Minnesota: Lessons From State Reform Efforts." *Journal of the American Medical Association*. October 8, 1997; 14: tzj1191.
[xiv] Agency for Healthcare Research and Quality, "Strategies to Prevent Crowd-out". Available online at: http://www.ahcpr.gov/chip/content/crowd_out/crowd_out_strategies.htm.
[xv] Ibid.
[xvi] Pear.
[xvii] Goldberg, Robert, Ph.D. "*Ten Myths About the Market for Prescription Drugs*." National Center for Policy Analysis, Policy Report No. 230, October 1999.
[xviii] Soumerai, Stephen B., Ross-Degnan, Dennis, Avorn, Jerry, McLaughlin, Thomas J., Choodnovisky, "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes" *The New England Journal of Medicine.* 1991: 325(15): 1072-1077.
[xix] Soumerai, Stephen B., Ross-Degnan, Dennis, "Inadequate Prescription Drug Coverage for Medicare Enrollees – A Call to Action (Sounding Board.)" *The New England Journal of Medicine*. 1999: 340(9): 722-728.
[xx] "Medicaid Cap on Drugs Lead to Higher Costs," September 9, 1994. Available online at: http:\\www.med.harvard.edu/publications/Focus/1994/Sept9_1994/Medicaid.html.
[xxi] Ross, Betsy McCaughey, "Drugs for elderly can save, not sink Medicare." *USA Today*, January 11, 1999.
[xxii] Soumerai, p. 725.
[xxiii] Harvard Medical School Office of Public Affairs, "Researchers Propose New Medicare Drug Coverage Plan for Low-Income Beneficiaries." News Release, March 1, 1999.
[xxiv] Pear.